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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,604	10/19/2001	James G. Clough	09166.002002	8156

22511 7590 05/05/2004

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EXAMINER

MOHANDESI, JILA M

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 05/05/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/032,604

Applicant(s)

CLOUGH ET AL.

Examiner

Jila M Mohandesi

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 3-20, 24-39 and 43-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21-23 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 08, 2004 has been entered.

Election/Restrictions

2. Claims 3-20, 24-39 and 43-55 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-2 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothbart (6,092,314). Rothbart '314 discloses an orthopedic appliance, comprising a wedge (60) for placement beneath a toe, (since feet come in different sizes, the orthopedic appliance can fall in different spot depending on the size of the foot), having a first upper surface disposed between a first end and an apex, a second upper surface,

disposed between the apex and a second end (See Figure 9 embodiment), the first upper surface being separated from a lower planar surface by an angle of inclination between 1 and 60 degrees in a direction substantially parallel to a medial column of the foot. See column 6, lines 66-67 and column 7, lines 1-9.

Inasmuch as applicant has failed to give a reference point for determining which end of the bone applicant is referring to as the distal end, hence the distal end (A) of the proximal phalanx of Rothbart '314 is clearly raised with respect to the distal end (B) of the first metatarsal as shown in the attached marked up Figure 6 embodiment.

Column 7, lines 9-19 disclose that the orthopedic appliance can also slope downwardly or taper as it extends toward the front edge (60) or toward the back edge as shown in Figure 12 embodiment. Therefore, the orthopedic appliance does incline a direction substantially parallel to the medial column of the foot. If there is any doubt that the angle of inclination is between 1 and 60 degrees, Rothbart '314 discloses that the angle of inclination of the apparatus can vary for a person with different foot structure such as severe hyperpronation and Rothbart's foot structure (see column 10, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the angle of inclination of the orthopedic device to better comfort and fit the feet of the user.

Claims 40-42 are directed to the obvious method of using the orthopedic appliance of Rothbart '314, which elevates a proximal phalanx to a predetermined angle of inclination using the wedge, relative to a first metatarsal, and improves stability of the foot.

5. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rothbart '314. Rothbart '134 discloses an apparatus for orthopedic treatment, comprising a first upper surface adapted to support a proximal phalanx; a second upper surface adapted to support a distal phalanx; a bottom surface (72); and a support (60), which maintains the proximal phalanx at an angle of inclination between the first upper surface and the bottom surface, relative to a first metatarsal. See column 6, lines 66-67, column 7, lines 1-9, and column 7, lines 9-19 and previously attached Figure 10 embodiment. The angle of inclination appears to be between 1 and 60 degrees. If there is any doubt that the angle of inclination is between 1 and 60 degrees, Rothbart '134 discloses that the angle of inclination of the apparatus can vary for a person with different foot structure such as severe hyperpronation and Rothbart's foot structure (see column 10, lines 33-36). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the angle of inclination to better comfort and fit the feet of the user.

Response to Arguments

6. Applicant's arguments filed March 08, 2004 have been fully considered but they are not persuasive.

Inasmuch as applicant has failed to give a reference point for determining which end of the bone applicant is referring to as the distal end, hence the distal end of the proximal phalanx of Rothbart '168 is clearly raised with respect to the distal end of the first metatarsal as shown in the attached marked up Figure 6 embodiment.

In response to applicant's argument that the orthopedic appliance comprises a wedge **for** placement beneath a toe and forward of the center of a first metatarsal, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, since feet come in different sizes, the orthopedic appliance can fall in different spot depending on the size of the foot.

In response to applicant's comment about the Examiner's lack of guidance in suggesting language that may be more acceptable in furtherance of the prosecution of this application, the Examiner does not see any patentable subject matter and therefore is not required to suggest any language.

Contrary to applicant's argument the configuration of the foot support system of Rothbart '314 clearly shows the proximal phalanx inclined with respect to a first metatarsal. See Figure 6 embodiment.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Shown are orthopedic appliances analogous to applicant's instant invention.

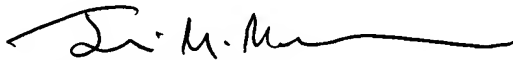
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jila M Mohandesi whose telephone number is (703) 305-7015. The examiner can normally be reached on Monday-Friday 7:30-4:00 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (703) 308-2672. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JILA M. MOHANDESI
PRIMARY EXAMINER



Jila M Mohandesi
Primary Examiner
Art Unit 3728

JMM
April 30, 2004